Supplement to

INFORMATION LETTER

NATIONAL CANNERS ASSOCIATION

No. 1783 Washington, D. C. June 18, 1960

FDA REGULATION UNDER FOOD ADDITIVE LAW

(from Federal Register of June 15, 1960)

PART 121—FOOD ADDITIVES

Subpart A—Definitions and Procedural and Interpretative Regulations

EXTENSION OF EFFECTIVE DATE OF STATUTE FOR CERTAIN SPECIFIED FOOD ADDITIVES

The Commissioner of Food and Drugs, pursuant to the authority provided in the Federal Food, Drug, and Cosmetic Act (sec. 6(c), Pub. Law 85-929; 72 Stat. 1788; 21 U.S.C., note under sec. 342) and delegated to him by the Secretary of Health, Education, and Welfare (23 F.R. 9500), hereby authorizes the use in foods of certain additives for which tolerances have not yet been established or petitions therefor denied.

Section 121.86 (25 F.R. 343, 404, 1074, 1727, 1944, 2203, 2837, 3525) is amended by adding thereto the following items:

§ 121.86 Extension of effective date of statute for certain specified food additives as direct additives to foods.

On the basis of data supplied in accordance with § 121.85 and findings that no undue risk to the public health is involved and that conditions exist that make necessary the prescribing of an additional period of time for obtaining tolerances or denials of tolerances or for granting exemptions from tolerances, the following additives may be used in food, under certain specified conditions, for a period of 1 year from March 6, 1960, or until regulations shall have been issued establishing or denying tolerances or exemptions from the requirement of tolerances, in accordance with section 409 of the act, whichever occurs first:

* * * * *

FLAVORING SUBSTANCES AND NATURAL SUBSTANCES USED IN CONJUNCTION WITH FLAVORS

Common name	*Botanical or zoological name of source*
Agaric, white	Polyporus officinalis fries.
Alkanet root	Alkanna tinctoria Tausch.
Aloe	Aloe perryi Baker, A. barbadensis Mill., A. ferox Mill., and hybrids of this species with A. africana Mill. and A. spicata Baker.
Aloe extract	Do.
Aloe, cape	Aloe ferox Mill. and its hybrids with A. africana Mill. and A. spicata Baker.
Aloe, cape, extract	Do.
Aloin	Aloe perryi Baker, A. barbadensis Mill., A. ferox Mill., and hybrids of this species with A. africana Mill. and A. spicata Baker.
Althea flowers (marshmallow)	Althea officinalis L.
Althea root (marshmallow root)	Do.
Amyris (West Indian sandalwood) oil	Amyris balsamifera L.
Angola weed	Roccella fuciformis Ach.
"Araucaria" oil	Callitropsis araucarioides Compt.
Artemisia (wormwood) (thujone free)	Artemisia spp.
Balsam fir oil	Abies balsamea (L.) Mill.
Balsam fir, oleoresin	Do.
Beechwood creosote	Fagus spp.
Benzoin gum (resin)	Styrax benzoin Dryand., S. parallelioneurus Perkins, S. tonkinensis (Pierre) Craib & Hartwich, or other spp. of the Section Authostyrax of the genus Styrax.
Birch tar oil, refined (rectified)	Betula pendula Roth and related Betula spp.
Blessed thistle (holly thistle) herb	Cnicus benedictus L.
Blessed thistle (holly thistle) herb extract, solid.	Do.
Blessed thistle (holly thistle) herb extract.	Do.
Blessed thistle (holly thistle) herb oil	Do.
Blackberry bark extract	Rubus, Sec. Eubatus.
Borage	Borago officinalis L.
Boronia, absolute	Boronia megastigma Nees.
Buchu leaves oil	Barosma betulina Bartl., B. crenulata (L.) Hook, and B. serratifolia Willd.
Buckbean leaves extract	Menyanthes trifoliata L.
Bugleweed, yellow (groundpine bugle)	Ajuga chamaepitys (L.) Schreb.
Bugleweed, yellow (groundpine bugle), extract.	Do.
Bugleweed, yellow (groundpine bugle), extract, solid.	Do.
Cabreuva oil	Myrocarpus frondosus Fr. Allen and M. fastigiatus Fr. Allen.
Cade oil (juniper tar, empyreumatic wood oil).	Juniperus oxycedrus L.
Cajeput (cajuput) oil	Melaleuca leucadendron L. and other Melaleuca spp.
Calamus (sweetflag)	Acorus calamus L.
Calamus oil	Do.
California laurel leaves extract	Umbellularia californica Nutt.
California laurel oil	Do.
Calumba	Jateorhiza palmata (Lam.) Miers.
Calumba extract	Do.
Carmine	Coccus cacti L.
Cascara, bitterless extract	Rhamnus purshiana DC.
Cassie absolute	Acacia farnesiana Willd.
Cassia fistula (goldenshower senna)	Cassia fistula L.
Castor oil	Ricinus communis L.
Catechu, black, extract	Acacia catechu Willd.
Catechu, black, powder	Do.
Cedar leaf oil	Thuja occidentalis L.
Cedarwood, American, white, oil	Juniperus virginiana L.
Centaury (centaurium) herb	Centaurium umbellatum Gilib.
Cherry-laurel water (laurocerasus wa-	Prunus laurocerasus L.

FLAVORING SUBSTANCES AND NATURAL SUBSTANCES USED IN CONJUNCTION WITH FLAVORS—Con.

Common name	*Botanical or zoological name of source*
Chestnut leaves	Castanea dentata (March.) Borkh.
Chestnut leaves extract	Do.
Chestnut leaves extract, solid	Do.
Chirata (chiretta, East Indian balmony)	Swertia chirayita (Roxb.) Lyons.
Chirata (chiretta, East Indian balmony) herb extract.	Do.
Cinchonidine	Cinchona spp. (α-quinidine).
Cire d'abeille, absolute	Apis mellifera L.
Cochineal	Coccus cacti L.
Cocillana bark	Guarea rusbyi (Britt.) Rusby.
Copaiba (balsam copaiba)	Copaifera spp.
Copaiba (balsam copaiba) oil	Do.
Cork, oak	Quercus suber L. and Q. occidentalis F. Gay.
"Costus root" extract	Saussurea lappa Clarke.
"Costus root" oil	Do.
Cramp bark extract	Viburnum trilobum Marsh.
Cubeb	Piper cubeba L. f.
Cubeb oil	Do.
Cudbear	Rocella spp., Lecanora spp., or other lichens.
Cudbear extract	Do.
Currant, black, buds, absolute	Ribes nigrum L.
Currant, black, buds, extract, solid	Do.
Currant, black, leaves	Do.
Damar gum	Shorea spp.
Davana oil	Artemisia pallens Wall.
Deer's-tongue (vanilla trilisa) extract	Trilisa odoratissima (Walt.) Cass.
Dittany (fraxinella)	Dictamnus albus L.
Dittany of Crete	Origanum dictamnus L.
Dittany of Crete, extract	Do.
Dittany of Crete extract, solid	Origanum dictamnus L.
Dittany of Crete oil	Do.
Dock, yellow, root	Rumex crispus L. or R. obtusifolius L.
Dock, yellow, root extract	Do.
Dock, yellow, root extract, solid	Do.
Dragon's blood	Daemonorops spp.
Elder flowers, with stems	Sambucus canadensis L. or S. nigra L.
Elder tree leaves	Sambucus nigra L.
Elecampane root	Inula helenium L.
Elecampane root extract	Do.
Elecampane root oil	Do.
Elemi gum	Canarium luzonicum (Miq.) A. Gray.
Elemi oil	Do.
Erigeron oil	Erigeron canadensis L.
Eucalyptus leaves	Eucalyptus globulus Labill. or other Eucalyptus spp.
Eucalyptus oil	Do.
Forget-me-not	Myosotis spp.
Galbanum oil	Ferula galbaniflua Boiss. et Buhse and other Ferula spp.
Galbanum resin	Do.
Gambir (catechu, pale)	Uncaria gambir (Hunter) Roxb.
Genet absolute	Spartium junceum L.
Genet extract	Do.
Gentian	Gentiana lutea L.
Gentian root extract	Do.
Germander, chamaedrys	Teucrium chamaedrys L.
Germander, chamaedrys, extract	Do.
Germander, chamaedrys, extract, solid	Do.
Guaiac wood oil	Guaiacum officinale L. and G. sanctum L.
Guaiac gum extract	Do.
Guaiac wood extract	Do.
Guarana	Paullinia cupana Kunth.

FLAVORING SUBSTANCES AND NATURAL SUBSTANCES USED IN CONJUNCTION WITH FLAVORS—Con.

Common name	*Botanical or zoological name of source*
Hart's-tongue	Phyllitis scolopendrium (L.) Newm.
Haw bark, black, extract	Viburnum prunifolium L.
Ho (ho-sho) oil	Cinnamomum camphora Sieb.
Iceland moss	Cetraria islandica Ach.
Imperatoria (masterwort)	Imperatoria ostruthium L.
Iva (musk yarrow)	Achillea moschata Jacq.
Labdanum absolute	Cistus spp.
Labdanum oil	Do.
Labdanum oleoresin	Do.
Lemon-verbena	Lippia citriodora H. B. and K.
Lettuce, wild	Lactuca scariola L., L. virosa L., or other Lactuca spp.
Linaloe wood oil	Bursera delpechiana Poiss. and related Bursera spp.
Linden flowers and leaves	Tilia spp.
Logwood chips extract	Haematoxylon campechianum L.
Lovage	Levisticum officinale Koch.
Lovage extract	Do.
Lovage oil	Do.
Lungmoss (lungwort)	Sticta pulmonacea Ach.
Manna	Fraxinus ornus L.
Maple, mountain, bark	Acer spicatum Lam.
Maple, mountain, bark, extract, solid	Do.
Maple, mountain, extract, solid	Do.
Meadowsweet, European (spiraea ulmaria).	Filipendula ulmaria (L.) Maxim.
Melilot herb (yellow melilot)	Melilotus officinalis (L.) Lam.
Mimosa absolute	Acacia decurrens Willd. var. dealbata.
Motherwort	Leonurus cardiaca L.
Mullein flowers	Verbascum phlomoides L. or V. thapsiforme Schrad.
Myrrh gum and oil	Commiphora molmol Engl., C. abyssinica (Berg) Engl., and other Commiphora spp.
Oak moss absolute (mousse de chene) and extract.	Evernia prunastri (L.) Ach. (true oak moss), E. furfuracea (L.) Mann, and other lichens.
Olibanum oil (frankincense)	Boswellia carteri Birdw. and other Boswellia spp.
Opopanax (bisabol-myrrh) gum and oil.	Opopanax chironium Koch (true opopanax), or Commophora erythraea Engl. var. glabrescens.
Passion flower herb extract	Passiflora incarnata L.
Patchouly oil	Pogostemon cablin Benth. and P. heyneanus Benth.
Peach leaves	Prunus persica Sieb. et Zucc.
Pennyroyal (American falsepennyroyal)	Hedeoma pulegioides (L.) Pers.
Pennyroyal (American falsepennyroyal) oil.	Do.
Pennyroyal (European pennyroyal mint).	Mentha pulegium L.
Pennyroyal (European pennyroyal mint) oil.	Do.
Pimpinella (pimpernel) root	Pimpinella saxifraga L. or P. magna L.
Pine, Scotch, oil	Pinus sylvestris L.
Pine, white, bark	Pinus strobus L.
Pine, white, bark oil	Do.
Pine, white, bark extract, solid	Do.
Poplar buds	Populus candicans Ait. or P. tacamahaca Mill. (P. balsamifera L.)
Quassia	Picrasma excelsa (Sw.) Planch. or Quassia amara L.
Quassia chips	Do.
Quassia root	Do.
Quassia extract	Do.
Quebracho bark extract	Aspidosperma quebracho-blanco Schlecht.
Quillaia extract (soapbark extract, China bark extract).	Quillaja saponaria Molina.

FLAVORING SUBSTANCES AND NATURAL SUBSTANCES USED IN CONJUNCTION WITH FLAVORS—Con.

Common name	Botanical or zoological name of source
Quinine hydrochloride	Cinchona spp.
Quinine sulfate	Do.
Red saunders (red sandalwood)	Pterocarpus santalinus, L.f.
Rhatany root	Krameria triandra Ruiz et Pav. or K. argentea Mart.
Rhatany extract	Do.
Rhubarb extract	Rheum officinale Baill., R. palmatum L. or other spp. (excepting R. rhaponticum), or hybrids of Rheum grown in China and Tibet.
Rhubarb root	Do.
Rosin (colophony)	Pinus palustris Mill. and other Pinus spp.
Saffron, American (safflower)	Carthamus tinctorius L.
St. Johnswort	Hypericum perforatum L.
Sandalwood (East Indian sandalwood)	Santalum album L.
Sandalwood (East Indian sandalwood) extract.	Do.
Sandalwood (East Indian sandalwood) extract, solid.	Do.
Sandalwood (East Indian sandalwood) oil.	Do.
Saponin, from soap bark (see quillaia extract).	
Sarsaparilla bark	Smilax aristolochiaefolia Mill. (Mexican sarsaparilla), S. regelii Killip et Morton (Honduras sarsaparilla), S. febrifuga Kunth (Ecuadorean sarsaparilla), or undetermined spp. of Smilax (Ecuadorean and Central American sarsaparilla).
Sarsaparilla extract	Do.
Sassafras leaves (contain no safrole)	Sassafras albidum (Nutt.) Nees.
Snakeroot, Canadian (Canada wild ginger), oil.	Asarum canadense L.
Sourwood leaves	Oxydendrum arboreum (L.) DC.
Spikenard, American, root	Aralia racemosa L.
Stargrass (starwort)	Aletris farinosa L.
Storax (styrax) extract	Liquidambar orientalis Mill. or L. styraciflua L.
Storax (styrax) gum	Do.
Tagetes (marigold) extract	Tagetes patula L., T. erecta L., or T. glandulifera Schrank.
Tagetes (marigold) oil	Do.
Tansy flowers	Tanacetum vulgare L.
Tansy flowers extract	Do.
Tansy flowers extract, solid	Do.
Tansy oil	Do.
Tolu balsam extract	Myroxylon balsamum (L.) Harms.
Tolu balsam gum	Do.
Tormentilla root	Potentilla tormentilla Neck. (Potentilla erecta).
Turpentine gum	Pinus palustris Mill. and other Pinus spp.
Turpentine, steam distilled	Do.
Valerian root	Valeriana officinalis L.
Valerian root extract	Do.
Valerian root oil	Do.
Veronica	Veronica officinalis L.

FLAVORING SUBSTANCES AND NATURAL SUBSTANCES USED IN CONJUNCTION WITH FLAVORS—Con.

Common name	Botanical or zoological name of source
Vervain, blue	Verbena hastata L.
Vetiver	Vetiveria zizanioides Stapf.
Vetiver extract	Do.
Vetiver oil	Do.
Violet flowers	Viola odorata L.
Wintersbark	Drimys winteri Forst.
Witch-hazel	Hamamelis virginiana L.
Woodruff, sweet, herb	Asperula odorata L.
Wormseed oil	Chenopodium ambrosioides L. var. anthelminticum (L.) Gray.
Yarrow herb	Achillea millefolium L.
Yerbasanta	Eriodictyon californicum (Hook. et Arn.) Torr.
Yerbasanta, fluidextract	Do.
Yucca brevifolia extract	Yucca brevifolia Engelm.
Yucca mohavensis root extract	Yucca mohavensis Sarg.

Notice and public procedure are not necessary prerequisites to the promulgation of this order, and I so find, since extensions of time, under certain conditions, for the effective date of the food additives amendment to the Federal Food, Drug, and Cosmetic Act were contemplated by the statute as a relief of restrictions on the food-processing industry.

Effective date. This order shall be effective as of the date of signature.

(Sec. 701, 52 Stat. 1055, as amended; 21 U.S.C. 371. Interpret or apply 72 Stat. 1088; 21 U.S.C., note under sec. 342)

Dated: June 9, 1960.

[SEAL] JOHN L. HARVEY,
Deputy Commissioner of Food and Drugs.

[F.R. Doc. 60-5439; Filed, June 14, 1960; 8:48 a.m.]

PART 121—FOOD ADDITIVES

Subpart A—Definitions and Procedural and Interpretative Regulations

EXTENSION OF EFFECTIVE DATE OF STATUTE FOR CERTAIN SPECIFIED ADDITIVES

The Commissioner of Food and Drugs, pursuant to the authority provided in the Federal Food, Drug, and Cosmetic Act (sec. 6(c), Public Law 85-929; 72 Stat. 1788; 21 U.S.C., note under sec. 342) and delegated to him by the Secretary of Health, Education, and Welfare (23 F.R. 9500), hereby authorizes the use in foods of certain additives for which tolerances have not yet been established or petitions therefor denied:

1. Section 121.86 (25 F.R. 343, 404, 1074, 1727, 2203, 2536, 2837, 3525) is amended by adding thereto the following items:

§ 121.86 Extension of effective date of statute for certain specified food additives as direct additives to food.

On the basis of data supplied in accordance with § 121.85 and findings that no undue risk to the public health is involved and that conditions exist that make necessary the prescribing of an additional period of time for obtaining tolerances or denials of tolerances or for granting exemptions from tolerances, the following additives may be used in food, under certain specified conditions, for a period of 1 year from March 6, 1960, or until regulations shall have been issued establishing or denying tolerances or exemptions from the requirement of tolerances, in accordance with section 409 of the act; whichever occurs first:

* * * * *

Product	Limits	Specified uses or restrictions
• • •	• • •	• • •
Bithionol and methiotriasamine mixture...	500 parts per million bithional; 100 parts per million methiotriasamine.	In poultry feed as a coccidiostat. Discontinue feed 3 days before marketing the birds to allow for elimination of the drug from edible tissue.
Ethylene oxide	50 parts per million	In dehydrated or freeze-dried mushrooms as residue from use as fumigant. In edible gums, as a residue from use as a fumigant.
Lactic acid esters of mono- and diglycerides derived by glycerolysis of edible vegetable and animal fat.		As emulsifiers in foods in accordance with good manufacturing practice.
Piperonyl butoxide and pyrethrins mixture.	30 parts per million piperonyl butoxide; 3 parts per million pyrethrins.	As residues in dried citrus pulp for animal feed from treating the stored pulp in burlap bags for insect control. Data demonstrates no residues in milk from feeding lactating dairy animals citrus pulp with these additives at or below the amounts listed.
Polyethylene glycols having molecular weights from 200 through 6,000.		As components of coatings or binders for tableted foods, in accordance with good manufacturing practice.

2. Section 121.87 *Extension of effective date of statute for certain specified food additives as indirect additives to food* (25 F.R. 1727, 1772, 2203, 3526) is amended in the following respects:

a. Paragraph (a) (25 F.R. 1727, 2203) is amended by changing the item "Maleic acid • • •" to read:

Product	Limits	Specified uses or restrictions
Maleic acid		Not to exceed 0.8 percent in nitrocellulose-coated, heat-sealing cellophane for packaging foods.

b. Paragraph (a) *General list* is further amended by adding thereto the following items:

§ 121.87 Extension of effective date of statute for certain specified food additives as indirect additives to food.

On the basis of data supplied in accordance with § 121.85 and findings that no undue risk to the public health is involved and that conditions exist that make necessary the prescribing of an additional period of time for obtaining tolerances or denials of tolerances or for granting exemptions from tolerances, the following additives may be used in connection with the production, packaging, and storage of food products, under certain specified conditions, for a period of 1 year from March 6, 1960, or until regulations shall have been issued in accordance with section 409 of the act, whichever occurs first. The extensions are granted under the condition that a minimum quantity of the additive will be incorporated in the food, consistent with good manufacturing practice. While preliminary data show that many of the substances included in the list may not migrate to foods, these are being included pending the completion of additional scientific work involving them.

(a) *General list.*

Product	Limits	Specified uses or restrictions
• • •	• •	• • •
Amine, secondary (hexadecyl, octadecyl) of hard tallow.		As constituent of defoaming agent used in manufacture of food-packaging materials.
Copolymers of styrene and divinyl benzene with added groups: quaternary ammonium, methyl, ethanol (from varying ratios).		
Copolymers of divinyl benzene and methacrylic or acrylic acid (from varying ratios).		
Copolymers of styrene and divinyl benzene with sulfonic acid groups (from varying ratios).		As ion-exchange resins used in food processing.
Copolymers of divinyl benzene and styrene (from varying ratios) with following added groups: Polyalkylamine, copolymers of divinyl-benzene and acrylic or methacrylic acid with added amine groups.		
Starch ether from reacting cornstarch with propylene oxide.		As a migrant from cotton fabrics used in dry food packaging.
Monoethanol amine		As a constituent of defoaming agent used in manufacture of food-packaging materials and adhesives.
Polyoxyalkylene glycols having molecular weights from 900 through 4,000.		As a constituent of defoaming agent used in boiler water treatment, glue manufacture, and bottle-washing detergent for food processing and packaging purposes, and lubricant for food-processing and packaging machinery.
Polyethylene glycols having molecular weights from 200 through 6,000.		As a component of release agents, coatings, adhesives, inks, and plasticizers used in food-packaging materials.
Polyoxyethylene glycol ester of mixed fatty acids from tall oil (average 16 oxyethylene groups).		As constituent of defoaming agent used in manufacture of food-packaging materials.
Polyoxyethylene sorbitol hexaoleate (average 60 oxyethylene groups).		
Polypropylene glycol having a molecular weight of 1,200.		

c. In paragraph (d) *Substances migrating from linings of containers used in food packaging,* subparagraph (5) is amended to read as follows:

(5) Rosin derivatives, including modification by polymerization, isomerization, decarboxylation, hydrogenation, and methyl ester of hydrogenated rosin:

(i) Rosin esters formed by reaction with:

Bisphenol-epichlorohydrin (epoxy).
Diethylene glycol.
Ethylene glycol.
Glycerol.
Methanol.
Pentaerythritol.

(ii) Rosin esters modified by reaction with maleic anhydride; ortho-, meta-, and para-substituted phenol-formaldehydes listed in subparagraph (6) of this paragraph; phenol-formaldehyde.

(iii) Calcium rosinate (limed rosin); zinc rosinate.

d. Paragraph (d) (7) is amended to read as follows:

(7) Polyester resins (including alkyd type) formed as ester of acids in subdivisions (i) and (ii) of this subparagraph, by reaction with polyhydric alcohols in subdivision (iii) of this subparagraph:

(i) Polybasic acids:

Adipic.
Dimerized fatty acids derived from oils listed in subparagraph (1) of this paragraph.
Fumaric.
Isophthalic.
Maleic.
Orthophthalic.
Rosin-maleic acid adduct (petrex acid).
Sebacic.
Terephthalic.
Trimellitic.

(ii) Monobasic acids:

Benzoic.
Fatty acids derived from oils listed in subparagraph (1) of this paragraph.
Rosins and rosin acids (see subparagraph (5) of this paragraph).
Tertiary butyl benzoic.

(iii) Polyhydric alcohols:

Diethylene glycol.
Ethylene glycol.
Glycerol.
Mannitol.
α-Methyl glucoside.
Pentaerythritol.
Propylene glycol.
Sorbitol.
Trimethylol ethane.
Trimethylol propane.

e. Paragraph (d) (8) is amended by adding thereto the following item:

Allyl ether of mono-, di-, or trimethyl phenol.

f. Paragraph (d) (14) is amended by adding thereto the following item:

Methyl-ethyl-butyl or octyl esters of acrylic acid copolymerized with acrylonitrile.

g. Paragraph (d) (25) is amended by adding thereto the following item:

18, 19, and 20 carbon alkyl amides.

h. Paragraph (d) is further amended by adding thereto the following new subparagraph (29):

(29) Dimethylpolysiloxane.

This order was effective June 8. (end of order and end of Supplement)